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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,795	09/10/1999	JOHN T. GRAY	CMCC693P2A	3301

21005 7590 06/03/2003

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/393,795

Applicant(s)

GRAY, ET AL.

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,11,15,19,21,26,30,34 and 38-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-10,12-14,16-18,20,22-25,27-29,31-33 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/03 has been entered.

Receipt is acknowledged of a response filed 3/17/03 as Paper No. 23. An evidentiary declaration by one of the inventors, Dr. John T. Gray, was filed as part of the response in Paper No. 23. This declaration has been considered in full. Claims 1-49 are pending in the instant application, with claims 4, 6, 11, 15, 19, 21, 26, 30, 34 and 38-49 withdrawn from consideration as directed to nonelected inventions.

This action is not final because of a new grounds of rejection made herein that was not necessitated by applicant's response in Paper No. 23.

Response to Evidentiary Declaration/Applicant Arguments

The Declaration filed by Dr. John T. Gray under 37 CFR 1.132 filed 3/17/03 is sufficient to overcome the rejection of claims 1-3, 5, 7-10, 12-14, 16-18, 20, 22-25, 27-29, 31-33, 35-37 based upon a lack of sufficient enablement for embodiments lacking a rev response element (RRE). The data obtained by Dr. Gray's group demonstrates that a vector described in the instant application as pHDMHgpm2 which lacks any of the HIV accessory protein coding sequences, a CTE and RRE is able to express codon-optimized

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gagpol at high levels. The Response filed 3/17/03 also cites a post-filing reference, Kotsopoulou et al (J. Virology, 2000, 74(10):4839-4852), in support of the proposition that the instant application is enabling. Together with the declaration provided by Dr. Gray, this evidence is found convincing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 7-10, 12-14, 16-18, 20, 22-25, 27-29, 31-33, 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This is a new rejection.

Claims 1, 5, 7-8, 12, 16, 20, 22-2327, 31, 35 comprise the limitation of a first nucleic acid sequence "...which comprises a codon optimized coding sequence for a HIV *gagpol* but not coding sequences for HIV accessory proteins, Rev response element or constitutive transport elements...". A reasonable interpretation of the cited phrase is that it specifies that the first nucleic acid sequence lacks either coding sequences for at least some HIV accessory proteins, or a rev response element (RRE) or constitutive transport element (CTE). This is contrary to what has been prosecuted and to what appears to be described in the instant specification. It would be remedial to amend the claim language to explicitly state that the first nucleic acid sequence of the invention lacks any of the HIV coding sequences, a RRE and a constitutive transport element (CTE).

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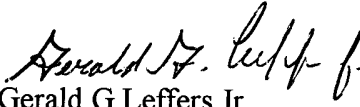
Conclusion

No claims are allowed. The claims appear to be free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
June 2, 2003